



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,338	03/01/2004	Ajay K. Luthra	2177.16US02	9411
24113	7590	11/16/2005	EXAMINER	
PATTERSON, THUENTE, SKAAR & CHRISTENSEN, P.A. 4800 IDS CENTER 80 SOUTH 8TH STREET MINNEAPOLIS, MN 55402-2100			KRUER, KEVIN R	
			ART UNIT	PAPER NUMBER
			1773	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/790,338

Applicant(s)

LUTHRA ET AL.

Examiner

Kevin R. Kruer

Art Unit

1773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 25 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-154 is/are pending in the application.
- 4a) Of the above claim(s) 1-53 and 105-150 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 54-104 and 151-154 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/2/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Claims 1-53 and 105-150 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 25, 2005.

2. Applicant's election with traverse of Group II in the reply filed on August 25, 2005 is acknowledged. The traversal is on the ground(s) that the search of all the claims would not pose an undue burden. This is not found persuasive because the groups contain patentably distinct inventions, which have separate status in the art. Thus, a search of both groups would require searching additional classes/subclasses.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

3. The information disclosure statement filed June 2, 2004 has been fully considered. An initialed copy of said IDS is enclosed herein.

Drawings

4. The drawings filed 3/1/2004 are accepted.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 54-104 and 151-154 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

Art Unit: 1773

subject matter which applicant regards as the invention. Said claims state the molecular weight of the polymer but do not state how the molecular weight is determined. Since a polymer's molecular weight is highly dependent upon the method utilized to measure said property, the claim must specify the method utilized or the "type" (number average, weight average, etc) of molecular weight claimed.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 54-75, 77, 84, 92-104, and 151-154 are rejected under 35 U.S.C. 102(e) as being anticipated by Alvarado et al (US 6,530,950).

Alvarado teaches a stent for insertion into a lumen wherein the stent is coated with a polymer (abstract). The polymer comprises 10-98% of a first monomer composed of an aliphatic ester C1-C50 of acrylic acid which when homogenized has a glass transition temperature lower than about 25C, and a second monomer having sites of unsaturation capable of copolymerizing with the first monomer and having a glass transition temperature of greater than 25C (col 2, lines 50+). For example, the first monomer may comprise butyl acrylate (col 2, lines 62+) and is herein relied upon to

Art Unit: 1773

read on the claimed first copolymer. The second monomer may comprise an ester of a methacrylic acid such as butyl methacrylate (col 3, lines 1+), and is herein relied upon to read on the first monomer. The polymer may further comprise 2-40wt% polyethylene glycol methacrylate (col 3, lines 25+). Said polyethylene glycol methacrylate is herein understood to read on the claimed "third monomer unit" of claim 57. Said terpolymer is understood to be taught with sufficient specificity to teach the terpolymer of claim 69. Furthermore, since the terpolymer is taught to be a "polymer," it is understood to necessarily have a molecular weight above 2500. The polymer may comprise an alternating copolymer formed by step polymerization, random or block copolymer (col 7, lines 1+) and preferably has a glass transition temperature of less than 25C (col 7, lines 45+). The coating further comprises a therapeutic agent (col 14, lines 7+) such as paclitaxel (col 14, lines 30+).

With regards to the relative glass transition temperature limitations of claims 54, 60, 61, 64, 96, 97, and 102, the monomers taught by Alvarado inherently meets said glass transition temperature limitations because said monomers are the same as those utilized by applicant. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable (MPEP2112.01).

With regard to claims 70 and 72, said limitations are method limitations that do not patentably distinguish a claimed product from a product taught in the prior art unless it can be shown that the method of making inherently results in a materially different product. No such showing has been made.

With regards to claims 75, 77, 84, Alvarado teaches the coating may be applied to the stent via an adhesive such as fluorinated polymers, heparin, collagen, and fibrin (col 13, lines 57+).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 76 and 78-83, 85 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alvarado et al (US 6,530,950), as applied to claims 54-75, 77, 84, 92-104, and 151-154 above, and further in view of Lentz et al (US 2002/0133183A).

Alvarado is relied upon as above, but does not teach the application of a heparin layer to said copolymer layer. However, Lentz teaches that it is well known in the art to apply heparin to coat biomaterials in order to prevent clotting (0115). Said herapin is photo-activated in order to form covalently bonds with the surface to which it is applied (0117). Thus, it would have been obvious to one of ordinary skill in the art to coat the stent taught in Alvarado with herapin in order to prevent clotting.

With respect to claim 85, the examiner takes the position that any coating will reduce the rate of release of the therapeutic agent to some extent.

11. Claims 86-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alvarado et al (US 6,530,950), as applied to claims 54-75, 77, 84, 92-104, and 151-154 above, and further in view of Sahatjian et al (US 5,843,089).

Art Unit: 1773

Alvarado is relied upon as above, but does not teach coating said stent with an acrylic, vinyl alcohol, or polyvinyl pyrrolidone coating. However, Sahatjian teaches lining a stent with a hydrogel in order to reduce shear forces and flow disturbances in the bloc, protect, damaged cells adjacent to the stent, and reduce platelet deposition. Said hydrogel may comprise, an acrylate, polyvinyl pyrrolidone, or PVOH. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply any of said hydrogels to the stent taught in Alvarado. The motivation for doing so would have been to reduce shear forces and flow disturbances in the bloc, protect, damaged cells adjacent to the stent, and reduce platelet deposition.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin R. Kruer whose telephone number is 571-272-1510. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on 571-272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Kevin R. Kruer". The signature is fluid and cursive, with the first name "Kevin" and last name "Kruer" clearly distinguishable.

Kevin R. Kruer
Patent Examiner-Art Unit 1773